Regence

Medical Policy Manual Durable Medical Equipment, Policy No. 80

Myoelectric and Microprocessor Prosthetic and Orthotic Components for the Upper Limb

Effective: April 1, 2026

Next Review: June 2026
Last Review: March 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Myoelectric prostheses and orthotics are powered by electric motors with an external power source. The joint movement of upper limb prostheses or orthoses (e.g., hand, wrist, and/or elbow) is driven by microchip-processed electrical activity in the muscles of the remaining limb or limb stump. Microprocessor controlled orthoses use feedback from sensors to adjust joint movement on a real-time as-needed basis to replace muscle activity in the affected limb.

MEDICAL POLICY CRITERIA

I. Myoelectric upper limb prostheses may be **medically necessary** when all of the following criteria are met (A. – F.):

A. The individual has an amputation or missing limb at the wrist or above (forearm, elbow, etc.); and

B. Standard body-powered prosthetic devices cannot be used or are insufficient to meet the functional needs of the individual (see Policy Guidelines); and

C. The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device, as demonstrated by functional testing using a physical or computer model prosthesis; and

D. The individual has demonstrated sufficient neurological and cognitive function to operate the prosthesis effectively; and

E. The individual is free of comorbidities that could interfere with function of the prosthesis (neuromuscular disease, etc.); and

F. Functional evaluation by a qualified professional (e.g., prosthetist) indicates that with training, use of a myoelectric prosthesis and associated components is necessary to meet the functional needs of the individual (see Policy Guidelines; e.g., automatic grasp features, microprocessor control features, or other components to aid gripping, releasing, holding, and coordinating movement of the prosthesis). This evaluation should consider the individual's needs for control, durability (maintenance), function (speed, work capability), and usability. Both of the following criteria must be met (1. and 2.):

1. The device is necessary for the individual's functional needs (see Policy Guidelines); and

2. The device is *not* primarily for the purpose of allowing the individual to perform leisure or recreational activities (see Policy Guidelines).

II. The replacement of all or part of an existing myoelectric upper limb prosthesis is considered **medically necessary** when the existing myoelectric upper limb prosthesis is malfunctioning, cannot be repaired, and is no longer under warranty OR when the current prosthetic can no longer meet the individual's functional needs (see Policy Guidelines) due to a significant change in the individual's physiological condition.

III. Replacement of all or part of an existing myoelectric upper limb prosthesis is considered **not medically necessary** when Criterion II. is not met.

IV. Myoelectric upper limb prosthetic components are considered **not medically necessary** under all other conditions.

V. Upper-limb prosthetic components with both sensor and myoelectric control are considered **investigational**.

VI. Myoelectric or microprocessor controlled upper-limb orthoses are considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

Functional Needs

For member contracts subject to Washington HB 1699 or Oregon SB 699: Devices that meet the needs of the individual for purposes of performing physical activities, including but not limited to activities of daily living (ADLs), running, biking, swimming and strength training. For these members, these would not be considered recreational activities.

For all other contracts: Devices that meet the needs of the individual for purposes of performing activities of daily living (ADLs).

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of amputation or missing limb at the wrist or above
- Documentation that standard body-powered devices can't be used or are not efficient including the ADLs and/or physical activities that cannot be accomplished currently
- Documentation that the remaining musculature in the limb contains the minimum microvolt threshold to allow operation of the device including a functional test using a physical or computer model prosthesis
- Documentation the individual is cognitively and neurologically able to operate the prosthetic
- Documentation the individual doesn't have any comorbidities that might interfere with the use of the prosthetic
- An evaluation by a qualified professional such as a prosthetist that shows the individual will be able to use the prosthetic for ADLs including the individual's ability to control, maintain, function, and use the prosthetic including why it is necessary for the individual to perform ADLs, job functions, and/or physical activities
- Documentation that the prosthetic is not being requested to replace a functioning prosthetic

CROSS REFERENCES

1. Definitive Lower Limb Prostheses, Durable Medical Equipment, Policy No. 18
2. Powered Knee Prosthesis, or Powered Ankle-Foot Prosthesis, and Microprocessor-Controlled Ankle-Foot Prosthesis, Durable Medical Equipment, Policy No. 81
3. Powered Exoskeleton for Ambulation, Durable Medical Equipment, Policy No. 89
4. Mechanical Residual Limb Volume Management System for Upper Extremity Prostheses, Durable Medical Equipment, Policy No. 98

BACKGROUND

Upper limb prostheses are used following amputation at any level from the hand to the shoulder. The need for a prosthesis can occur for a number of reasons, including trauma, surgery, or congenital anomalies. The primary goals of the upper limb prosthesis are to restore natural appearance and function. Achieving these goals also requires sufficient comfort and ease of use for continued acceptance by the wearer. The difficulty of achieving these diverse goals with an upper limb prosthesis increases as the level of amputation (digits, hand, wrist, elbow, and shoulder), and thus the complexity of joint movement, increases.

Upper limb prostheses are classified based on the means of generating movement at the joints as follows:

PASSIVE PROSTHESIS:

- The lightest weight upper extremity prosthesis
- Individuals generally describe this as the most comfortable of the three types
- Must be repositioned manually, typically by moving it with the opposite arm

- Cannot restore function.

BODY-POWERED PROSTHESIS

- Uses a body harness and cable system to provide functional manipulation of the elbow and hand. Voluntary movement of the shoulder and/or limb stump extends the cable and transmits the force to the terminal device.
- Prosthetic hand attachments, which may be claw-like devices that allow good grip strength and visual control of objects or latex-gloved devices that provide a more natural appearance at the expense of control, can be opened and closed by the cable system.
- Complaints with body-powered prostheses include harness discomfort, particularly the wear temperature, wire failure, and the unattractive appearance.

MYOELECTRIC PROSTHESIS

Uses muscle activity from the remaining limb for the control of joint movement.

- Electromyographic (EMG) signals from the limb stump are detected by surface electrodes, amplified, and then processed by a controller to drive battery-powered motors that move the hand, wrist, or elbow.
- Implantable EMG sensors with wireless signal transmission (e.g., Implantable Myoelectric Sensors [IMES®]) are being studied as alternatives to surface electrodes to improve prosthetic hand function. These implantable sensors may eliminate the limitations inherent in surface electrodes such as issues related to poor skin contact (e.g., skin sweating) and the ability to detect signals only from superficial muscles.
- Although upper arm movement may be slow and limited to one joint at a time, myoelectric control of movement may be considered the most physiologically natural.
- Myoelectric hand attachments are similar in form to those offered with the body-powered prosthesis, but are battery powered.
- Dissatisfaction with myoelectric prostheses includes the increased cost, maintenance (particularly for the glove), and weight.
- Examples of available technologies:
    - The SensorHand™ by Advanced Arm Dynamics, which is described as having an AutoGrasp feature, an opening/closing speed of up to 300 mm/second, and advanced EMG signal processing.
    - The Utah Arm 3 by Motion Control has a microprocessor interface that allows individualized adjustments to achieve maximum performance.
    - The i-LIMB™ hand (Touch Bionics), sometimes referred to as the bionic hand, is the first commercially available myoelectric hand prosthesis with individually powered digits.
    - ProDigits™, also from Touch Bionics, are prosthetic digits for one or more fingers for amputation at a transmetacarpal level or higher.
    - Otto Bock has a number of myoelectric hand and elbow prostheses including the AutoGrasp feature, the Michelangelo® Hand, and the Electrohand 2000 designed for children.
    - LTI Boston Digital Arm™ System by Liberating Technologies Inc. is marketed as having greater torque than any other powered prosthetic elbows
    - These devices may be covered by LIVINGSKIN™, a high-definition silicone prosthesis created to resemble natural skin.

SENSOR AND MYOELECTRIC PROSTHESIS

The LUKE Arm (previously known as the DEKA Arm System) can perform complex tasks with multiple simultaneous powered movements (e.g., movement of the elbow, wrist, and hand at the same time). In addition to the EMG electrodes, the LUKE Arm contains a combination of mechanisms including switches, movement sensors, and force sensors. The Luke Arm is the same shape and weight as an adult arm.

HYBRID SYSTEM, A COMBINATION OF BODY-POWERED AND MYOELECTRIC COMPONENTS

- May be used for high-level amputations (at or above the elbow).
- Allows control of two joints at once (i.e., one body-powered and one myoelectric)
- Generally lighter weight and less expensive than a prosthesis composed entirely of myoelectric components.
- An example of a hybrid system is the ErgoArm by Otto Bock which has a myoelectric hand and a cable-controlled elbow joint

Technology in this area is rapidly changing, driven by advances in biomedical engineering and by the U.S. Department of Defense Advanced Research Projects Agency (DARPA), which is funding a public and private collaborative effort on prosthetic research and development. Areas of development include the use of skin-like silicone elastomer gloves, “artificial muscles,” and sensory feedback. Smaller motors, microcontrollers, implantable myoelectric sensors, and re-innervation of remaining muscle fibers are being developed to allow fine movement control. Lighter batteries and newer materials are being incorporated into myoelectric prostheses to improve comfort.

MYOELECTRIC ORTHOSES

The MyoPro (Myomo) is a myoelectric powered upper-extremity orthotic. This orthotic device weighs about 1.8 kilograms (4 pounds), has manual wrist articulation, and myoelectric initiated bi-directional elbow movement. The MyoPro detects weak muscle activity from the affected muscle groups. A therapist or prosthetist/orthoptist can adjust the gain (amount of assistance), signal boost, thresholds, and range of motion. Potential users include individuals with traumatic brain injury, spinal cord injury, brachial plexus injury, amyotrophic lateral sclerosis, and multiple sclerosis. Use of robotic devices for therapy has been reported. The MyoPro is the first myoelectric orthotic available for home use.

MICROPROCESSOR ORTHOSES

A microprocessor controlled orthosis is an orthotic device that integrates sensors, a microprocessor-based control unit, and actuators into an orthosis to support everyday movements. By continuously capturing joint angles, load, and speed, the device dynamically adjusts joint support and resistance to improve stability and energy efficiency. Typical users include individuals with neuromuscular disorders, post-stroke impairments, spinal cord injury, or limb weakness. The Carbonhand (Bioservo) is an assistive device in the form of a grip-strengthening glove, with pressure sensors that detect when the user initiates a grip and then applies the power needed to ensure a firm grip. The Carbonhand enhances the force applied by the user. By compensating for the loss of grip strength and hand function, the user can perform daily activities that previously found difficult to perform or unable to perform without the glove.

Regulatory Status

Prostheses are class I devices that are exempt from U.S. Food and Drug Administration (FDA) marketing clearance, but manufacturers must register prostheses with the restorative devices branch of the FDA and keep a record of any complaints.

Examples of available myoelectric technologies are listed above.

The MyoPro® (Myomo) and Carbonhand (Bioservo) are registered with the FDA as a class 1 limb orthosis.

EVIDENCE SUMMARY

In evaluating the effects of the increased sophistication of myoelectric upper limb prostheses compared with body-powered prostheses, passive prostheses, or no prosthesis, the most informative data are from prospective comparative studies with objective and subjective measures that directly address function and health-related quality of life.

In light of the magnitude of functional loss in upper extremity amputation, evaluation of the evidence is based on two assumptions:

1. Use of any prosthesis confers clinical benefit, and
2. Self-selected use is an acceptable measure of the perceived benefit (combination of utility, comfort, and appearance) of a prosthesis for that individual.

It should be considered that the upper limb amputee's needs may depend on their situation. For example, increased functional capability may be needed with heavy work or domestic duties, while a more natural appearing prosthesis with reduced functional capability may be acceptable for an office, school, or another social environment.

MYOELECTRIC UPPER LIMB PROSTHESIS

Systematic Reviews

A 2015 systematic review (SR) by Carey evaluated differences between myoelectric and body-powered prostheses. The SR included 31 studies.[1] The evidence was conflicting for functional performance between the two prostheses. The authors concluded that there is insufficient evidence to show that one system provides a significant advantage over the other and that prosthetic selection should be based on patient preference and functional needs.

A 2007 SR by Biddis of 40 articles published over the previous 25 years assessed upper limb prosthesis acceptance and abandonment.[2] For pediatric patients the mean rejection rate was 38% for passive prostheses (one study), 45% for body-powered prostheses (three studies), and 32% for myoelectric prostheses (12 studies). For adults there was considerable variation between studies, with mean rejection rates of 39% (six studies), 26% (eight studies), and 23% (10 studies) for passive, body-powered and myoelectric prostheses, respectively. The authors found no evidence that the acceptability of passive prostheses had declined over the period from 1983 to 2004, "despite the advent of myoelectric devices with functional as well as cosmetic appeal." Body-powered prostheses were also found to have remained a popular choice, with the type of hand-attachment being the major factor in acceptance. Body-powered hooks were considered acceptable by many users, but body-powered hands were frequently

rejected (80% to 87% rejection rates) due to slowness in movement, awkward use, maintenance issues, excessive weight, insufficient grip strength, and the energy needed to operate. Rejection rates of myoelectric prostheses tended to increase with longer follow-up. There was no evidence of a change in rejection rates over the 25 years of study, but the results are limited by sampling bias from isolated populations and the generally poor quality of the studies included.

Randomized Controlled Trials

Touillett (2023) published the results of a monocentric, randomized, controlled, cross-over trial evaluating shoulder abduction and manual dexterity in transradial amputees (N = 8) fitted with two prosthetic myoelectric hooks, the Greifer and the Axon-Hook.[3] They also made comparisons with the non-affected (NA) side. Shoulder abduction was significantly higher with the Greifer (60.9 ± 20.3, p = 0.03) than with the Axon-Hook (39.8 ± 16.9) and also than with the NA side (37.6 ± 19.4, p = 0.02). Shoulder abduction on the NA side (37.6 ± 19.4) was close to that of the Axon-Hook (39.8 ± 16.9). There was no difference between devices or with the NA side in the percentage of time spent with shoulder abduction > 60 during the Box Block Test (BBT). A significant strong negative correlation was found between shoulder abduction and wrist position with the Axon-Hook (r = -0.86; p < 0.01), but not with the Greifer. Manual dexterity and satisfaction did not differ significantly between the two devices.

In comparative studies of prostheses, subjects served as their own control. Since these studies included use by all subjects of both a myoelectric and a body-powered prosthesis, randomization was directed at the order in which each amputee used the prostheses. Two trials were found in which a total of 196 children used both a myoelectric and a body-powered hand prosthesis, in randomized order, for a period of three months each.[4, 5] No clinically relevant objective or subjective difference was found between the two types of prostheses.

Nonrandomized Studies

A number of small (n<50) non-randomized case series[6-8] and online, telephone, or mailed surveys[9-13] were found, but few studies directly addressed whether myoelectric prostheses improved function and health-related quality of life. Most of the studies identified described amputees' self-selected use or rejection rates. The results were usually presented as hours worn at work or school, hours worn at home, and hours worn in social situations. Amputees' self-reported reasons for use and abandonment were also frequently reported. The limited evidence available suggests that, in comparison with body-powered prostheses, myoelectric components may improve range of motion to some extent, have similar capability for light work, but may have reduced performance under heavy working conditions. The literature also indicated that the percentage of amputees who accepted use of a myoelectric prosthesis was about the same as those who prefer to use a body-powered prosthesis, and that self-selected use depended at least in part on the individual's activities of daily living. Appearance was most frequently cited as an advantage of myoelectric prostheses. Nonuse of any prosthesis was associated with lack of functional need, discomfort (excessive weight and heat), and impediment to sensory feedback.

Section Summary: Myoelectric Upper-Limb Prosthesis

The identified literature focuses primarily on patient acceptance and rejection; data are limited or lacking in the areas of function and functional status. The limited evidence suggests that the percentage of amputees who accept a myoelectric prosthesis is approximately the same as

those who prefer to use a body-powered prosthesis, and that self-selected use depends partly on the individual's activities of daily living. When compared with body-powered prostheses, myoelectric components possess similar capability to perform light work, and myoelectric components may improve range of motion. The literature has also indicated that appearance is most frequently cited as an advantage of myoelectric prostheses, and for patients who desire a restorative appearance, the myoelectric prosthesis can provide greater function than a passive prosthesis with equivalent function to a body-powered prosthesis for light work.

SENSOR AND MYOELECTRIC UPPER LIMB COMPONENTS

Investigators from three Veterans Administration medical centers and the Center for the Intrepid at Brooke Army Medical Center published a series of reports on home use of the LUKE prototype (DEKA Gen 2 and DEKA Gen 3) in 2017 and 2018.[14-18] Participants were included in the in-laboratory training if they met criteria and had sufficient control options (e.g., myoelectric and/or active control over one or both feet) to operate the device. In-lab training included a virtual reality training component. At the completion of the in-lab training, the investigators determined, using a priori criteria, which participants were eligible to continue to the 12-week home trial. The criteria included the independent use of the prosthesis in the laboratory and community setting, fair, functional performance, and sound judgment when operating or troubleshooting minor technical issues.

One of the publications (Resnick, 2017) reported on the acceptance of the LUKE prototype before and after a 12-week trial of home use.[16] Of 42 participants enrolled at the time, 32 (76%) participants completed the in-laboratory training, 22 (52%) wanted to receive a LUKE Arm and proceeded to the home trial, 18 (43%) completed the home trial, and 14 (33%) expressed a desire to receive the prototype at the end of the home trial. Over 80% of those who completed the home trial preferred the prototype arm for hand and wrist function, but as many preferred the weight and look of their own prosthesis. One-third of those who completed the home training thought that the arm was not ready for commercialization. Participants who completed the trial were more likely to be prosthesis users at study onset ($p=0.03$), and less likely to have musculoskeletal problems ($p=0.047$).[14] Reasons for attrition during the in-laboratory training were reported in a separate publication by Resnik and Klinger (2017).[17] Attrition was related to the prosthesis entirely or in part by 67% of the participants, leading to a recommendation to provide patients with an opportunity to train with the prosthesis before a final decision about the appropriateness of the device.

Functional outcomes of the Gen 2 and Gen 3 arms, as compared with participants' prostheses, were reported by Resnick et al (2018).[15] At the time of the report, 23 regular prosthesis users had completed the in-lab training, and 15 had gone on to complete the home use portion of the study. Outcomes were both performance-based and self-reported measures. At the end of the lab training, dexterity was similar, but performance was slower with the LUKE prototype than with their conventional prosthesis. At the end of the home study, activity speed was similar to the conventional prostheses, and one of the performance measures (Activities Measure for Upper-Limb Amputees) was improved. Participants also reported that they were able to perform more activities, had less perceived disability, and less difficulty in activities, but there were no differences between the two prostheses on many of the outcome measures including dexterity, prosthetic skill, spontaneity, pain, community integration, or quality of life. Post hoc power analysis suggested that evaluation of some outcomes might not have been sufficiently powered to detect a difference.

In a separate publication, Resnick (2017) reported that participants continued to use their prosthesis (average, 2.7 h/d) in addition to the LUKE prototype, concluding that availability of both prostheses would have the greatest utility.[18] This conclusion is similar to those from earlier prosthesis surveys, which found that the selection of a specific prosthesis type (myoelectric, powered, or passive) could differ depending on the specific activity during the day. In the DEKA Gen 2 and Gen 3 study reported here, 29% of participants had a body-powered device, and 71% had a conventional myoelectric prosthesis.

Section Summary: Sensor and Myoelectric Upper-Limb Components

The LUKE Arm was cleared for marketing in 2014 and is now commercially available. The prototypes for the LUKE Arm, the DEKA Gen 2 and Gen 3, were evaluated by the U.S. military and Veteran's Administration in a 12-week home study, with study results reported in a series of publications. Acceptance of the advanced prosthesis in this trial was mixed, with one-third of enrolled participants desiring to receive the prototype at the end of the trial. Demonstration of improvement in function has also been mixed. After several months of home use, activity speed was shown to be similar to the conventional prosthesis. There was an improvement in the performance of some, but not all, activities. Participants continued to use their prosthesis for part of the day, and some commented that the prosthesis was not ready for commercialization. There were no differences between the LUKE Arm prototype and the participants' prostheses for many outcome measures. Study of the current generation of the LUKE Arm is needed to determine whether the newer models of this advanced prosthesis lead to consistent improvements in function and quality of life.

MYOELECTRIC ORTHOTIC

Page (2020) compared the efficacy of a myoelectric orthosis combined with repetitive task-specific practice to repetitive task-specific practice alone in improving performance for subjects with post-stroke upper extremity hemiparesis.[19] A total of 34 patients with chronic, moderate, stable, post-stroke, upper extremity hemiparesis were randomly assigned to Myomo + repetitive, task-specific practice; repetitive, task-specific practice only; or Myomo only. The primary outcome was the upper extremity section of the Fugl-Meyer Impairment Scale and the secondary outcome was the Arm Motor Activity Test. The groups all increased on the Fugl-Meyer Impairment Scale and the Arm Motor Activity Test, with no significant differences between groups.

Peters (2017) evaluated the immediate effect (no training) of a myoelectric elbow-wrist-hand orthosis on paretic upper-extremity impairment.[20] Participants (n=18) were stable and moderately impaired with a single stroke 12 months or later before study enrollment. They were tested using a battery of measures without, and then with the device; the order of testing was not counterbalanced. The primary measure was the upper-extremity section of the Fugl-Meyer Assessment, a validated scale that determines active movement. Upper-extremity movement on the Fugl-Meyer Assessment was significantly improved while wearing the orthotic (a clinically significant increase of 8.71 points, $p<0.001$). The most commonly observed gains were in elbow extension, finger extension, grasping a tennis ball, and grasping a pencil. The Box and Block test (moving blocks from one side of a box to another) also improved ($p<0.001$). Clinically significant improvements were observed for raising a spoon and cup, and there were significant decreases in the time taken to grasp a cup and gross manual dexterity. Performance on these tests changed from unable to able to complete. The functional outcome measures (raising a spoon and cup, turning on a light switch, and picking up a laundry basket

with two hands) were developed by the investigators to assess these moderately impaired participants. The authors noted that performance on these tasks was inconsistent, and proposed a future study that would include training with the myoelectric orthosis before testing.

Page (2013) compared the efficacy of a myoelectric orthosis combined with repetitive task-specific practice to repetitive task-specific practice alone in improving performance following stroke.[21] Sixteen subjects at a mean of 75 months post-stroke were divided into two groups. Both groups received therapist-supervised repetitive task-specific practice for three days a week for eight weeks. One group used the orthotic during practice. After intervention, there was no significant difference between groups in Fugl-Meyer score increases, six measures of the Stroke Impact Scale, or Canadian Occupational Performance Measure Performance. There was a significant difference in the Stroke Impact Scale Total ($p=0.027$).

Section Summary: Myoelectric Orthotic

The largest study identified tested participants with and without the orthosis. This study evaluated the function with and without the orthotic in stable poststroke participants who had no prior experience with the device. Outcomes were inconsistent. Studies are needed that show consistent improvements in relevant outcome measures. Results should also be replicated in a larger number of patients.

MICROPROCESSOR ORTHORIC

Randomized Controlled Trials

Radder (2019) conducted a pilot randomized controlled trial examining the effectiveness of a wearable soft-robotic device (ironHand glove) for improving hand function in older adults through home-based rehabilitation.[22] The study enrolled 91 adults with self-perceived hand function decline and were randomly assigned to either assistive use during daily activities, therapeutic use as a training tool, or a control group receiving no additional intervention over a 4 week period. Participants completed assessments including maximal pinch grip test, Box and Blocks test (BBT), and Jebsen-Taylor Hand Function Test (JTHFT) at baseline and post-intervention. The therapeutic group demonstrated improvements in unsupported handgrip strength and pinch strength after 4 weeks ($p\leq0.039$), with handgrip strength showing greater improvement compared to the assistive and control groups. Both intervention groups reported high system usability scores. However, improvements in BBT and JTHFT scores were observed across all groups, including controls, and no significant correlations were found between performance changes and assistive or therapeutic ironHand use ($p\geq0.062$). Study limitations include the study design with a small sample size, and the inability to isolate the specific effects of the intervention given that control group participants also showed improvements in some measures.

Nonrandomized Studies

Millkvist (2025) conducted a longitudinal case series on eight patients investigating whether a soft robotic glove (Carbonhand) could improve activity performance and body function for patients with brachial plexus birth injury (BPBI).[23] Eight patients with BPBI, used the soft robotic glove at home for three months, with data on activity performance, satisfaction with activity performance, active range of motion, and strength collected at baseline, three months, and four months. Patients completed an evaluation form at three months and maintained a diary for three out of 12 weeks. Results showed that six out of eight patients wanted to

continue using the device and improved their self-perception of activity performance and satisfaction with performance due to a more secure grip compared to when not using the device. All patients demonstrated improved maximum strength and endurance in elbow flexion at three months, with the device proving useful as both an assisting device and training tool. Study limitations include the small sample size, use of a convenience sample, reliance on self-reported outcomes for activity performance and satisfaction, incomplete diary data (only three out of 12 weeks), and no long-term follow-up assess sustained benefits.

Kottink (2024) conducted a multicenter intervention trial evaluating the therapeutic effect of a grip-supporting soft-robotic glove (Carbonhand) as an assistive device during daily activities at home.[24] The study enrolled 63 patients with chronic hand function limitations resulting from various disorders, using a design with three pre-assessments (averaged if steady state = PRE), one post-assessment (POST), and one follow-up assessment (FU). Participants used the glove on their most affected hand for six weeks in their home environment, with freedom to choose activities and duration of use. Primary outcome was grip strength, with secondary outcomes including pinch strength, hand function, and glove use time. Results demonstrated improvements from PRE to POST in grip strength (+1.9 kg, confidence interval [CI] 0.8 to 3.1, p=0.002), JTHFT score (-7.7 s, CI -13.4 to -1.9, p=0.002), and Action Research Arm Test scores (+1.0 point, interquartile range [IQR] 2.0, p≤0.001), with improvements persisting at follow-up. Pinch strength showed slight improvements across all fingers but did not achieve statistical significance. Participants used the glove for an average total of 330 min/week (or 47 min/day), with no serious adverse events reported. Study limitations include the lack of control group, heterogeneity of the patient population with various underlying disorders, high variability in glove usage time among participants.

Correia (2020) conducted a study evaluating the performance of a textile-based soft robotic glove controlled by the user with a button in thirteen participants with tetraplegia resulting from spinal cord injury.[25] Performance outcomes included activities of daily living using the JTHFT, active range of motion of the fingers, and grasp strength for power and pinch grasps. Results demonstrated improvements in performance of activities of daily living with glove assistance, with participants completing a median of 50% more tasks than in their baseline attempt without the glove. Improvements were also found for power and pinch grasp forces and active range of motion of the fingers with glove assistance. Participants with lower baseline motor function received greater benefits from glove assistance. Study limitations include the small sample size, lack of a control group, absence of long term follow up with assessments of effectiveness over time.

Osuagwu (2020) conducted a pilot study investigating the therapeutic effect of a self-administered home-based hand rehabilitation program using the soft extra muscle (SEM) Glove in people with chronic cervical spinal cord injury (SCI).[26] Fifteen participants were recruited and provided with the glove device to use at home for a minimum of 4 hours per day for 12 weeks while completing set tasks and performing usual activities of daily living. Assessments were conducted at Week 0 (Initial), 6, 12, and 18 (6-week follow-up), with the Toronto Rehabilitation Institute hand function test (TRI-HFT) as the primary outcome measure and pinch dynamometry and modified Ashworth scale as secondary measures. Results demonstrated improvement in hand function at Week 6, including object manipulation (58.3 ±3.2 to 66.9 ±1.8, p≈0.01) and palmar grasp assessed as the length of wooden bar held using pronated palmar grip (29.1 ±6.0 cm to 45.8 ±6.8 cm, p<0.01), with improvements in pinch strength and reduced thumb muscle hypertonia also detected. Improvements in function persisted at Week 12 and follow-up assessments. Study limitations include the small sample

size, lack of a control group, absence of blinding, restriction to participants with motor incomplete cervical SCI which limits generalizability, and the retrospective design which may introduce reporting bias.

Hashida (2019) conducted a clinical pilot study of 30 patients evaluating the effectiveness of motor-assisted gloves (SEM Glove) on grip and pinch strength in patients with functional finger disorders.[27] Thirty hospitalized patients with upper limb functional disorder were enrolled, with assistance of the device assessed by comparing measured values with and without the SEM Glove. Results showed that grip strength decreased when wearing the glove (worn-not worn difference (kg): mean = -3.7, CI 95 (-5.4, -2.1)), while pinch strength (thumb-middle finger) significantly increased (worn-not worn difference (N): mean = -4.1, CI 95 (1.6, 6.6)). Study limitations include the small sample size, lack of a control group, the unexpected finding of decreased grip strength with glove use which was not adequately explained, cross-sectional design without longitudinal follow-up, heterogeneous patient population, and absence of functional outcome measures beyond strength testing to assess impact on activities of daily living.

Section Summary: Microprocessor Orthotic

The identified literature includes a combination of randomized controlled trial and nonrandomized studies. The evidence is limited by small sample sizes, short intervention duration, inability to distinguish device effects from natural recovery, high variability in usage patters, lack of standardized functional outcomes, and absence of long-term follow up. Additional studies are needed with standardized outcome measures, homogeneous patient populations to establish specific indications, long intervention periods, and objective functional outcomes.

PRACTICE GUIDELINE SUMMARY

No practice guidelines identified.

SUMMARY

There is enough research to show that myoelectric upper limb prostheses improve health outcomes for people with an amputation or missing limb at the wrist or above when the medical policy criteria are met. Therefore, myoelectric upper limb prostheses may be considered medically necessary when policy criteria are met.

In certain situations, a myoelectric upper limb prosthesis may no longer be able to perform its basic function due to damage or wear. When it is out of its warranty period and cannot be repaired adequately to meet the individual's functional needs, replacement of the device may be medically appropriate. Therefore, replacement of all or part of a myoelectric upper limb prosthesis may be considered medically necessary when device replacement criteria are met.

When a myoelectric upper limb prosthesis is in its warranty period or can be repaired or adapted adequately to meet the individual's functional needs, replacement of the device is not medically appropriate. Therefore, replacement of all or part of a myoelectric upper limb prosthesis is considered not medically necessary when device replacement criteria are not met.

There is enough research to show that myoelectric upper limb prostheses do not improve health outcomes when policy criteria are not met. Therefore, myoelectric upper limb prostheses, under all other conditions including but not limited to replacement of an existing functioning prostheses are considered not medically necessary when policy criteria are not met.

There is not enough research to show that upper-limb prosthetic components with both sensor and myoelectric control improve health outcomes compared with conventional prostheses. Therefore, upper-limb prosthetic components with both sensor and myoelectric control are considered investigational.

There is not enough research to show that myoelectric or microprocessor controlled upper-limb orthoses improve health outcomes for any indication including upper limb weakness or paresis. Therefore, myoelectric or microprocessor controlled upper-limb orthoses are considered investigational.

REFERENCES

1. Carey SL, Lura DJ, Highsmith MJ. Differences in myoelectric and body-powered upper-limb prostheses: Systematic literature review. *J Rehabil Res Dev.* 2015;52(3):247-62. PMID: 26230500
2. Biddiss EA, Chau TT. Upper limb prosthesis use and abandonment: a survey of the last 25 years. *Prosthet Orthot Int.* 2007;31(3):236-57. PMID: 17979010
3. Touillet A, Billon-Grumillier C, Pierret J, et al. Comparison of compensatory shoulder movements, functionality and satisfaction in transradial amputees fitted with two prosthetic myoelectric hooks. *PloS one.* 2023;18(2):e0272855. PMID: 36730223
4. Kruger LM, Fishman S. Myoelectric and body-powered prostheses. *J Pediatr Orthop.* 1993;13(1):68-75. PMID: 8416358
5. Edelstein JE, Berger N. Performance comparison among children fitted with myoelectric and body-powered hands. *Arch Phys Med Rehabil.* 1993;74(4):376-80. PMID: 8466418
6. Silcox DH, 3rd, Rooks MD, Vogel RR, et al. Myoelectric prostheses. A long-term follow-up and a study of the use of alternate prostheses. *J Bone Joint Surg Am.* 1993;75(12):1781-9. PMID: 8258548
7. Egermann M, Kasten P, Thomsen M. Myoelectric hand prostheses in very young children. *Int Orthop.* 2009;33(4):1101-5. PMID: 18636257
8. James MA, Bagley AM, Brasington K, et al. Impact of prostheses on function and quality of life for children with unilateral congenital below-the-elbow deficiency. *J Bone Joint Surg Am.* 2006;88(11):2356-65. PMID: 17079391
9. Biddiss E, Chau T. Upper-limb prosthetics: critical factors in device abandonment. *Am J Phys Med Rehabil.* 2007;86(12):977-87. PMID: 18090439
10. Pylatiuk C, Schulz S, Doderlein L. Results of an Internet survey of myoelectric prosthetic hand users. *Prosthet Orthot Int.* 2007;31(4):362-70. PMID: 18050007
11. Berke GM, Fergason J, Milani JR, et al. Comparison of satisfaction with current prosthetic care in veterans and servicemembers from Vietnam and OIF/OEF conflicts with major traumatic limb loss. *J Rehabil Res Dev.* 2010;47(4):361-71. PMID: 20803404
12. McFarland LV, Hubbard Winkler SL, Heinemann AW, et al. Unilateral upper-limb loss: satisfaction and prosthetic-device use in veterans and servicemembers from Vietnam and OIF/OEF conflicts. *J Rehabil Res Dev.* 2010;47(4):299-316. PMID: 20803400

13. Resnik L, Borgia M, Clark M. Function and Quality of Life of Unilateral Major Upper Limb Amputees: Effect of Prosthesis Use and Type. *Arch Phys Med Rehabil.* 2020. PMID: 32437692
14. Resnik L, Cancio J, Klinger S, et al. Predictors of retention and attrition in a study of an advanced upper limb prosthesis: implications for adoption of the DEKA Arm. *Disability and rehabilitation Assistive technology.* 2018;13(2):206-10. PMID: 28375687
15. Resnik LJ, Borgia ML, Acluche F, et al. How do the outcomes of the DEKA Arm compare to conventional prostheses? *PloS one.* 2018;13(1):e0191326. PMID: 29342217
16. Resnik LJ, Borgia ML, Acluche F. Perceptions of satisfaction, usability and desirability of the DEKA Arm before and after a trial of home use. *PloS one.* 2017;12(6):e0178640. PMID: 28575025
17. Resnik L, Klinger S. Attrition and retention in upper limb prosthetics research: experience of the VA home study of the DEKA arm. *Disability and rehabilitation Assistive technology.* 2017;12(8):816-21. PMID: 28098513
18. Resnik L, Acluche F, Lieberman Klinger S, et al. Does the DEKA Arm substitute for or supplement conventional prostheses. *Prosthet Orthot Int.* 2017:309364617729924. PMID: 28905665
19. Page S, Griffin C, White S. Efficacy of myoelectric bracing in moderately impaired stroke survivors: A randomized, controlled trial. *Journal of rehabilitation medicine.* 2020;52(2). PMID: 31960066
20. Peters HT, Page SJ, Persch A. Giving them a hand: wearing a myoelectric elbow-wrist-hand orthosis reduces upper extremity impairment in chronic stroke. *Annals of rehabilitation medicine.* 2017;98(9):1821-27. PMID: 28130084
21. Page SJ, Hill V, White S. Portable upper extremity robotics is as efficacious as upper extremity rehabilitative therapy: a randomized controlled pilot trial. *Clin Rehabil.* 2013;27(6):494-503. PMID: 23147552
22. Radder B, Prange-Lasonder GB, Kottink AIR, et al. Home rehabilitation supported by a wearable soft-robotic device for improving hand function in older adults: A pilot randomized controlled trial. *PloS one.* 2019;14(8):e0220544. PMID: 31386685
23. Millkvist H, Kallstromer A, Bernspang B, et al. The impact of a soft robotic glove on activity performance and body function for brachial plexus birth injury patients-A longitudinal case series. *J Hand Ther.* 2025;38(2):297-305. PMID: 38937162
24. Kottink AIR, Nikamp CDM, Bos FP, et al. Therapy effect on hand function after home use of a wearable assistive soft-robotic glove supporting grip strength. *PloS one.* 2024;19(7):e0306713. PMID: 38990858
25. Correia C, Nuckols K, Wagner D, et al. Improving Grasp Function After Spinal Cord Injury With a Soft Robotic Glove. *IEEE Trans Neural Syst Rehabil Eng.* 2020;28(6):1407-15. PMID: 32305931
26. Osuagwu BAC, Timms S, Peachment R, et al. Home-based rehabilitation using a soft robotic hand glove device leads to improvement in hand function in people with chronic spinal cord injury:a pilot study. *J Neuroeng Rehabil.* 2020;17(1):40. PMID: 32138780
27. Hashida R, Matsuse H, Bekki M, et al. Evaluation of Motor-Assisted Gloves (SEM Glove) for Patients with Functional Finger Disorders: A Clinical Pilot Study. *Kurume Med J.* 2019;65(2):63-70. PMID: 30853689

CODES

Codes	Number	Description
CPT	None	
HCPCS	A8005	Powered, cable driven grip assist glove, hand, finger, includes microprocessor, pressure sensors, all components and accessories, custom fitted
	A8006	Powered, cable driven grip assist glove, hand, finger, includes pressure sensors, glove replacement only
	E1399	Durable medical equipment, miscellaneous
	L6026	Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)
	L6693	Upper extremity addition, locking elbow, forearm counterbalance
	L6700	Upper extremity addition, external powered feature, myoelectronic control module, additional emg inputs, pattern-recognition decoding intent movement
	L6715	Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement
	L6880	Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)
	L6881	Automatic grasp feature, addition to upper limb electric prosthetic terminal device
	L6882	Microprocessor control feature, addition to upper limb prosthetic terminal device
	L6925	Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6935	Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6945	Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6955	Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6965	Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L6975	Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
	L7007	Electric hand, switch or myoelectric controlled, adult
	L7008	Electric hand, switch or myoelectric controlled, pediatric
	L7009	Electric hook, switch or myoelectric controlled, adult
	L7045	Electric hook, switch or myoelectric controlled, pediatric
	L7180	Electronic elbow, microprocessor sequential control of elbow and terminal device
	L7181	Electronic elbow, microprocessor simultaneous control of elbow and terminal device
	L7190	Electronic elbow, adolescent, Variety Village or equal, myoelectronically controlled
	L7191	Electronic elbow, child, Variety Village or equal, myoelectronically controlled
	L7259	Electronic wrist rotator, any type

Codes	Number	Description
	L7499	Upper extremity prosthesis, not otherwise specified
	L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
	L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated

Date of Origin: *June 2010*